

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION THIS DOCUMENT RELATES TO: WAVE 1 CASES ON ATTACHED EXHIBIT A	Master File No. 2:12-MD-02327 MDL No. 2327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
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**PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT
OF DAUBERT MOTION TO PRECLUDE TESTIMONY
OF JUAN CARLOS FELIX, M.D.**

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INTRODUCTION

Dr. Felix is “board certified in Anatomic Pathology with added qualification in Cytopathology.” Exhibit B, Expert Report of Dr. Felix at p. 1. Plaintiffs do not challenge his qualifications as such. However, Dr. Felix seeks to offer testimony that is not helpful for the jury, clearly exceeds the bounds of his qualifications, and is founded on insufficient facts and unreliable methodology.¹

In his report, Dr. Felix does little more than contradict Plaintiffs’ expert, Dr. Iakovlev, and provide *ipse dixit* opinions. Indeed, his report reads less like a scientific expert report and more like a *Daubert* motion or a cross-examination of Dr. Iakovlev. This type of testimony will do little to explain the scientific principles at issue to the jury. Moreover, instead of relying upon (and citing to) scientifically reliable sources of information, Dr. Felix premises his opinions on speculation, statements made by defense counsel, his current recollection of 15-year old conversations, Google, or the simple fact that ‘he hasn’t seen it.’ Dr. Felix has not demonstrated the requisite reliability for his opinions on the analysis of polypropylene mesh pathology, including his critique of Dr. Iakovlev’s methodology and findings. Accordingly, he should be prevented from offering testimony or opinions as outlined below.

LEGAL STANDARD

For the sake of brevity and because the Court is fully aware of the legal standards governing the admissibility of expert testimony in the Fourth Circuit, Plaintiffs will not set forth a detailed discussion of the legal standard. It is known and understood that the admissibility of

¹ See *Phelan v. Synthes*, 35 Fed. Appx. 102, 105 (4th Cir. 2002) (the reasoning or methodology underlying testimony must be scientifically valid and able to be properly applied to the facts in issue.).

expert testimony is governed by the Federal Rules of Evidence, including but not limited to Rules 702, 403 and 104.² The trial judge acts as a gatekeeper for scientific, technical and other specialized knowledge.³

LEGAL ARGUMENT

A. Dr. Felix's testimony should be excluded—in its entirety—because his opinions (and his criticisms of Dr. Iakovlev) are not scientifically reliable or proper

Dr. Felix's experience in the field of anatomical pathology does not render all of his opinions admissible. Indeed, the admissibility of Dr. Felix's unreliable or unfounded opinions presents a serious risk of confusing the issues and misleading the jury in this case.⁴ As this Court noted, “[j]ust because an expert may be ‘qualified . . . by knowledge, skill, experience, training or education’ does not necessarily mean that the opinion that the expert offers is ‘the product of reliable principles and methods’ or that the expert ‘has reliably applied the principles and methods to the facts of this case.’”⁵

Dr. Felix provides only two opinions *of his own* in his report: (1) the body's “reaction to mesh”; and (2) “clinical pathological correlation.” Exhibit B, at 5-10. He then stops providing opinions of his own, and spends roughly 28 pages of his report attacking the credibility of Dr. Iakovlev and his opinions. Exhibit B, at 10-38. Dr. Felix criticizes Dr. Iakovlev on several issues, including: his understanding of anatomy; scarring and pain; structural changes; and degradation. But despite his strong disagreement with Dr. Iakovlev on so many subjects, Dr.

² See *Bryte v. Am. Household, Inc.*, 429 F.3d 469, 476 (4th Cir. 2005)(federal law governs admissibility of expert testimony).

³ See *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 587 (1993); *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 141 (1999).

⁴ See *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999) (“[T]he court must recognize that due to the difficulty of evaluating their testimony, expert witnesses have the potential to ‘be both powerful and quite misleading.’” (citing *Daubert*, 509 U.S. at 596)).

⁵ *Cisson v. C. R. Bard, Inc. (In re C. R. Bard, Inc.)*, 948 F. Supp. 2d 589, 612 (S.D. W. Va. 2013).

Felix does not cite to contrary scientific evidence that could establish that Dr. Iakovlev's opinions are unreliable.

The pertinent question to this Court's *Daubert* analysis is not whether or not Dr. Felix is right or wrong—and Plaintiffs do not *need* to challenge these opinions based on their accuracy—the pertinent question is whether Dr. Felix provided scientific support for his opinions.⁶ The answer to that question is: no, he did not. And the type of 'I don't believe it' and 'because I say so' *ipse dixit* testimony Dr. Felix seeks to proffer is not helpful to the jury—because it provides no scientific basis upon which the jury could rely.⁷

i. Dr. Felix's experience does not render his opinions and criticisms reliable

The underlying logic of the majority of Dr. Felix's opinions and criticisms is essentially: 'I have not seen it, so it does not happen.' For example, Dr. Felix does not believe that the TVT mesh contracts because he believes contracture would cause urinary obstruction—and he has not seen that in his practice. Exhibit C, Dep. of Dr. Felix (October 3, 2015) at 54:23-55:25; *see also* Exhibit B, at 13-14. However, it is understandable that Dr. Felix might not have personally experienced the relevant complications and issues—as he does not specialize in any area relevant to his opinions on the TVT mesh. For example, he is not board certified in gynecology or urogynecology, and has never implanted a sling device or treated a woman with stress urinary incontinence. Exhibit C, at 10:4-18; Exhibit D, 64:24-65:2; Exhibit E, at 7:16-20. He is not a materials chemist, or a biomedical engineer. Exhibit C, at 78:3-14. Additionally, Dr. Felix is not an expert on the design of transvaginal mesh, nor has he performed any research or independent testing on polypropylene mesh. According to Dr. Felix, he treats women with cervical, vaginal,

⁶ See *Westberry*, 178 F.3d at 261 (focus is on the principles and methodology, not the conclusions reached ... the court need not determine if expert testimony is irrefutable or necessarily correct).

⁷ *Ipse dixit* is defined as, "[h]e himself said it; a bare, assertion resting on the authority of an individual." See Black's Law Dictionary 828 (6th ed. 1990); *see also Sandow-Pajewski v. Busch Entertainment Corp.*, 55 F. Supp. 2d 422, 427 (E.D.Va. 1999).

and vulvar cancer precursors. Exhibit C, at 10:25-11:9. Simply put, he does not have any specialized education, training, or experience specifically related to polypropylene or the scientific, chemical or structural make-up of Ethicon medical devices and/or any of its components including polypropylene mesh. Therefore, what Dr. Felix has seen in his practice is of little import.

Moreover, Dr. Felix cannot reasonably rely upon his sporadic and undocumented review of explanted mesh as a basis for his opinions. Dr. Felix claims to have looked at more than fifty mesh specimens over the course of 22 years, most of which he examined around the year 2000 at the University of Southern California (USC). Exhibit C, at 50:10-51:10. However, while he claims to have “evaluate[d] the gross and histological characteristics of the tissue reaction associated with [the mesh]” (Exhibit B, at 3), he has not bothered to disclose the protocol or criteria for the collection, evaluation, or testing of these specimens. Furthermore, of the 50 plus specimens he examined, approximately 20 of them were removed for urinary obstruction due to the TVT being implanted with too much tension (to his knowledge). Exhibit C, at 52:12-19. Most alarming, Dr. Felix seeks to proffer opinions based upon his recollection of examining these specimens—with a concentration around the year 2000—without having reviewed a single slide or record relating to those explants, and without providing any sort of records or documentation to Plaintiffs. *Id.* at 59:14 – 60:20. Because Dr. Felix’s recollections cannot be confirmed or tested, they cannot be effectively rebutted; therefore, any opinions based upon his review of explanted mesh at USC are not proper “expert” testimony, as he has not provided a scientifically reliable basis or methodology for them.

ii. Dr. Felix has not sufficiently reviewed the facts or scientific literature for his opinions to be reliable

Dr. Felix cites to almost no scientific literature, studies, or other support for his disagreements with Dr. Iakovlev because he did not perform a comprehensive literature review. Instead, he relies upon the documents and literature that defense counsel selected for him. Exhibit D, at 19:7-11; Exhibit E, at 61:13-62:15. Under *Daubert*, a literature review must be performed appropriately in order to be part of a reliable methodology; as part of this, the Court must find more than an expert's own "hypothesis and speculation."⁸ Dr. Felix's review of articles hand-picked for him by defense counsel does not qualify as a literature review under *Daubert*. Because of this, his reliance on this cherry-picked literature does not provide any support for the argument that his opinions are scientifically reliable.

Similarly, Dr. Felix cannot establish the reliability of his opinions based upon his own research, experimentation, or testing of the pathological evidence in this case. Indeed, he does not even claim to rely upon his experimentation or testing of the material provided to him in this litigation. Specifically, both Plaintiff and defense experts were provided with equal amounts of pathology from the Plaintiffs' cases. However, Dr. Felix does not cite to, or rely upon any slides that he himself prepared—his opinions are based entirely upon the slides prepared, and the work performed, by Dr. Iakovlev. In sum, Dr. Felix has not used any scientific or medical methodology to support his opinions (or criticisms of Dr. Iakovlev), and expert speculation such as this should necessarily be excluded.⁹

B. Dr. Felix's opinions on degradation are not scientifically reliable

⁸ *Doe v. Ortho-Clinical Diagnostics, Inc.*, 440 F. Supp. 2d 465, 473-74 (M.D.N.C. 2006) (excluding expert testimony based on a literature review, stating that it must be based on more than "hypothesis and speculation," that the review was "disconnected" and not derived by the scientific method).

⁹ *Oglesby v. GMC*, 190 F.3d 244, 250 (4th Cir. 1999) ("A reliable expert opinion must be based on scientific, technical, or other specialized knowledge and not on belief or speculation, and inferences must be derived using scientific or other valid methods.").

Dr. Felix spends six pages of his report criticizing Dr. Iakovlev's degradation opinions. Exhibit B, 23-29. However, unlike Dr. Iakovlev's opinions, Dr. Felix's counter-opinions amount to nothing more than baseless assumptions. The law is clear that "unsupported speculation" of this nature is not only insufficient, but precisely what *Daubert* aims to prevent.¹⁰

During his October 3rd, 2015 deposition, Dr. Felix was asked to provide support for his opinion that polypropylene does not degrade *in vivo*. His response was simply that it must not degrade because it is still in use and—according to Dr. Felix—"still works." Exhibit C, at 83:15-84:6. As such, Dr. Felix's opinions appear to be premised on the *speculative assumption* that simply because polypropylene is still used in medical applications, it therefore does not degrade.

Dr. Felix also bases his opinion that degradation does not occur *in vivo* on the assertion that there is no literature on it.¹¹ However, the only literature Dr. Felix relies upon was provided to him by defense counsel. This fact alone—that he has ignored contradictory science—is justification for precluding him from providing any testimony regarding degradation.¹²

Additionally, Dr. Felix asserts that he does not "believe" that oxygenation would cause polypropylene to degrade, but he admits that he has not seen any data on the subject—and only claims to know the biochemistry "a little bit." Exhibit C, at 66:12-23. Despite not seeing any data, and only knowing a little bit about the biochemistry, Dr. Felix is still willing to proffer the opinion that "Ethicon experts have intentionally oxidized Prolene mesh, processed it using standard tissue processing protocols and attempted to stain it with H&E", and that "[t]he findings

¹⁰ *Brown v. Auto-Owners Ins. Co.*, No. 96-2613, 1997 U.S. App. LEXIS 23559, *3 (4th Cir., Sept. 8, 1997) (the expert's testimony must be grounded in the methods and procedures of science and not subjective belief or unsupported speculation); *see also Bryte v. Am. Household, Inc.*, 429 F.3d 469, 477 (4th Cir. 2005).

¹¹ Exhibit D.

¹² As this Court held in *Sanchez*, "An expert's opinion may be unreliable if he fails to account for contrary scientific literature and instead 'selectively [chooses] his support from the scientific landscape.' '[I]f the relevant scientific literature contains evidence tending to refute the expert's theory and the expert does not acknowledge or account for that evidence, the expert's opinion is unreliable.'" *Sanchez v. Boston Sci. Corp.*, No. 2:12-cv-05762, 2014 U.S. Dist. LEXIS 137189, *70 (S.D. W. Va. Sept. 29, 2014) (citations omitted).

from these experiments show that intentionally oxidized Prolene does not take up stain as Dr. Iakovlev posits.” Exhibit B, at 27. Here is the exchange during Dr. Felix’s October 15th, 2015 deposition regarding how he knows about these tests and their results:

Q. How do you know that happened?

A. I was told that it was -- that it happened by the attorneys at Butler Snow.

Q. Did you look at any of these documents associated with it?

A. No.

Q. So that comes straight out of the Butler Snow lawyers’ mouths?

A. Yes.

Exhibit C, at 84:21-86:4. Later, on re-direct, Dr. Felix suddenly remembered having read a report on Ethicon’s intentional oxidization of Prolene mesh, but still admitted that he did not know how Ethicon oxidized the mesh. *Id.* at 87:3-5. Subsequently, he conceded the mesh did degrade a certain amount during this testing, but did not know how much it degraded or what it looked like after being oxidized. *Id.* at 87:14-22. In short, Dr. Felix never questioned the purported findings fed to him by defense counsel—he simply regurgitated them in his report—and he knows next to nothing about the underlying testing or data.

Furthermore, Dr. Felix repeatedly refers to his “belief” or “hypothesis” regarding the cause of the bark that Dr. Iakovlev points to as evidence of in vivo degradation—Felix asserts that it forms after explantation—but never provides any support for that opinion. Exhibit C, at 73:13-76:17. Dr. Felix bases this completely untested hypothesis on his claimed understanding that temperature and xylene can degrade polypropylene, and that both are present in post-explant tissue processing. *Id.* However, he admits that he does not know the temperature at which polypropylene degrades—*i.e.*, he testified that Plaintiffs’ counsel should ask those types of questions (about the specifics of polypropylene degradation) to a materials scientist. *Id.* at 78:3-14. In addition, Dr. Felix learned that xylene could cause polypropylene to degrade because he “Googled” it—after being retained—and freely admitted to not being an expert on xylene

degradation. *Id.* at 78:23-79:23. Dr. Felix's "hypothesis" regarding the bark discussed by Dr. Iakovlev amounts to an uneducated guess based upon information that he recently found on the internet. He certainly should not be permitted to provide any opinions—including rebuttal opinions—relating to the presence of the bark. In sum, Dr. Felix has not studied degradation, and the majority of the knowledge he has on it apparently comes from Butler Snow. As such, his opinions pertaining to the degradation of transvaginal mesh are not scientifically reliable.

i. Opinions based on Dr. Felix's reliance of Defendant's expert Dr. Steven MacLean must be excluded

For the reasons set forth in Plaintiffs' *Motion and Memorandum to Exclude the Opinions and Testimony of the Defendant Ethicon, Inc's Expert Steven MacLean, and Plaintiffs' Reply to Defendant's Response in Opposition to Plaintiffs' Motion and Memorandum to Exclude the Opinions and Testimony of Defendant Ethicon, Inc's Expert Steven Maclean*, the opinions based on Dr. Felix's reliance of Dr. Steven MacLean must be excluded. See Exhibit F-G. Furthermore, Plaintiffs adopt and incorporate the arguments contained in *Plaintiffs' Daubert Motion to Exclude the Opinions and Testimony of Dr. Steven MacLean* that will be filed by May 12, 2016, in the wave one cases.

C. Dr. Felix's opinions on contracture are speculative and unreliable

It is a well-accepted principle that "an expert's proffered testimony is inadmissible 'when it is based on assumptions which are speculative and are not supported by the record.'"¹³ Further, neither *Daubert* nor the Federal Rules of Evidence require the admission of opinion evidence that is merely *ipse dixit* of the expert, and a court may conclude that there is too large of an

¹³ *Casey v. Geek Squad Subsidiary Best Buy Stores, L.P.*, 823 F. Supp. 2d 334, 340 (D.Md. 2011) (citing *Tyger Constr. Co. v. Pensacola Contr. Col.*, 29 F.3d 137, 142 (4th Cir. 1994)).

analytical gap between the data and the opinion proffered.¹⁴ Finally, opinions not premised in reliable scientific fact are not proper.¹⁵

Dr. Felix seeks to opine that the TVT mesh does not contract *in vivo*. Exhibit B, at 15. However, his opinions regarding this subject—*i.e.*, his belief that contraction does not occur—are nothing more than baseless assumptions and *ipse dixit* in the face of scientific literature to the contrary.

First, Dr. Felix has not performed any studies or testing relating to contraction of mesh. Further, he has not conducted a literature review relating to the issue. In fact, none of the documents he reviewed—hand selected for him by defense counsel—mention the topic of mesh contraction. Exhibit C, at 34:12-35:12. Despite having not conducted a literature review, Dr. Felix did admit that he is aware of literature showing contraction of mesh implanted in the abdomen; however, he could not explain why contraction would occur when polypropylene mesh is implanted in the abdomen, but not when implanted in the suburethral space. For example, during deposition, Dr. Felix stated:

I can't explain – I cannot explain why it would occur – necessarily explain why it would occur, if it does, in the abdomen. But I can – I can say *unequivocally*, that it does not occur in the suburethral space.

Id. at 33:25-34:4. Dr. Felix does not cite to any support for this “unequivocal” belief. In fact, Dr. Felix is so tied to this unsupported opinion that he later testified that even if he was shown Ethicon documents establishing *in vivo* contraction of mesh, he simply “would not believe them.” *Id.* at 35:22-36:5. This head-in-the-sand approach is not based on reliable science.

¹⁴ *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

¹⁵ See *Tyger Constr. Co.*, 29 F.3d at 144 (Stating that a “greater danger is that the jury may accept as fact not just the faulty assumptions on which [the expert] relied, but may also accept the conclusions that are drawn through his use of these assumptions. When the assumptions made by an expert are not based on fact, the expert’s testimony is likely to mislead the jury...”).

Indeed, an expert's disagreement with contrary literature without offering further explanation has previously been rejected by this Court.¹⁶ Therefore, Dr. Felix's failure to address and explain this literature contradicting his opinions—literature establishing that mesh contracts *in vivo*—is grounds for excluding his opinions on the subject.

D. Dr. Felix cannot opine that the TVT does not cause pain

As Dr. Felix makes clear in his report, the basis for his opinion that polypropylene mesh does not cause pain is that—“to his knowledge”—none of the women from which the explanted mesh he has examined experienced pain:

As previously mentioned, I have had the opportunity to examine over 50 explanted mesh specimens both grossly and microscopically in the past 22 years at USC. Approximately twenty of these samples were removed for urinary obstruction, where the suburethral sling was placed under excessive tension during surgery and obstructed the urethra. *To my knowledge, none of these women were experiencing pain.*”

Exhibit B, at 19. Indeed, the *only* basis that Dr. Felix provides for his opinion that the TVT does not cause pain, is to point to what he *understands* to be the experiences of women whose mesh he has examined.

These opinions are unreliable for several reasons. First, this Court has previously rejected the ‘I have not seen it, therefore it must not happen’ logic.¹⁷ Indeed, in ruling on *Daubert* motions in *Tyree*, the Court held that the “[a]bsence of evidence is not evidence of absence,” and refused to allow Defendant’s expert to opine that certain events do not occur simply because he had not observed them in his practice.¹⁸ By this same unassailable reasoning, Dr. Felix’s claim that as far as he knows the women whose mesh he examined did not experience

¹⁶ See *Sanchez v. Boston Sci. Corp.*, No. 2:12-cv-05762, 2014 U.S. Dist. LEXIS 137189, *32-33 (S.D. W. Va. Sept. 29, 2014) (“[I]f the relevant scientific literature contains evidence tending to refute the expert’s theory and the expert does not acknowledge or account for that evidence, the expert’s opinion is unreliable.”).

¹⁷ *Tyree v. Boston Sci. Corp.*, 54 F. Supp. 3d 501 (S.D. W. Va. 2014).

¹⁸ *Id.* at 583.

pain, cannot serve as a reliable scientific basis for opining that pain cannot occur as a result of mesh. Therefore, this unscientific testimony should be excluded.

Moreover, Dr. Felix cannot opine that these women did not experience pain with anything close to certainty. During his October 3rd, 2015 deposition, Dr. Felix admitted that he cannot say with one hundred percent certainty that the women whose explants he evaluated were not experiencing pain. Exhibit C, at 57:21-58:9. Simply put, he does not recall anyone mentioning that the women had reported pain during his discussions with other doctors—discussions which occurred 15 years ago. *Id.* at 57:1-58:10. Dr. Felix did not talk to the women at issue, did not ask them if they experienced pain, and does not even claim to have reviewed the records from their examinations—he just says he does not remember anyone mentioning that “the vast majority” of women were experiencing pain. *Id.* This is not a proper basis for reliable scientific expert opinion testimony.

The remainder of this section of Dr. Felix’s report—relating to mesh causing pain—amounts to nothing more than Dr. Felix’s unsupported assertions that Dr. Iakovlev is wrong. Dr. Felix has not provided scientific support for these contentions. Dr. Felix has not utilized *any* method—let alone a reliable method—to reach his conclusions relating to mesh causing pain. Again, Dr. Felix’s opinions amount to nothing more than unsupported speculation that must be excluded under *Daubert*.¹⁹

E. Cytotoxicity

On page 37 of Dr. Felix’s report, he includes one short paragraph attempting to proffer opinions regarding the cytotoxicity of TVT. Exhibit B, at 37. Dr. Felix cites to no studies, literature, or other scientific support for these opinions. Instead, the only support Dr. Felix offers

¹⁹ *Brown*, 1997 U.S. App. LEXIS 23559 at *3 (the expert’s testimony must be grounded in the methods and procedures of science and not subjective belief or unsupported speculation); *see also Bryte v. Am. Household, Inc.*, 429 F.3d 469, 477 (4th Cir. 2005).

for his opinion is the assertion that: (1) Dr. Iakovlev does not discuss cytotoxicity; and, (2) Dr. Felix has never personally noticed cytotoxicity in his own practice. First, the fact that Dr. Iakovlev has not rendered opinions on the subject has no bearing on whether the mesh in TVT is cytotoxic. Second, as this court has repeatedly held, the fact that Dr. Felix has not happened to notice cytotoxicity or particle loss with respect to the TVT mesh in his own practice is not sufficient to render a reliable opinion on the subject.²⁰

CONCLUSION

Ethicon, as the proponent of the expert testimony, bears the substantial burden of establishing that Dr. Felix is sufficiently qualified and that the proposed testimony satisfies the applicable evidentiary standards for the admission of expert testimony. Considering the lack of experience, knowledge, and reliability inherent in Dr. Felix's opinions, Ethicon cannot carry this burden and Dr. Felix's testimony should be excluded.

Dated: April 21, 2016

Respectfully submitted,

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²⁰ *Tyree*, 2014 U.S. Dist. LEXIS 155138, *183-85 (“[a]bsence of evidence is not evidence of absence”).

CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing document on April 21, 2016, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

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